



## Update on the Activities of the United Nations (UN) Subcommittee of Experts on the Transport of Dangerous Goods

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In December 2002, I had the opportunity to attend the United Nations (UN) Subcommittee of Experts on the Transport of Dangerous Goods at the Palais des Nations in Geneva, Switzerland. I represented ABSA, replacing Penny Holeman who had pioneered ABSA's involvement with this group along with ABSA supporters such as Steve Nash, formerly of Eli Lilly. Due to their efforts, ABSA was given "Observer" status.

The Subcommittee is made up of "Experts" from about 30 countries. These Experts are generally the heads of the Dangerous Goods Transport Departments in each of their countries, and depending on the issues being considered, they may bring other staff members to complete their delegations. In addition to the Experts, there are about 70 groups of "Observers." The Observers represent smaller countries, specialized government agencies (e.g., World Health Organization [WHO]), and nongovernmental organizations such as ABSA, IATA, and other groups. Only Experts can vote; however, Experts and Observers can comment on issues, make proposals for consideration by the committee, or offer technical information papers on various subjects.

The meetings are held twice each year. Their purpose is to work on the development/revisions of the Model Regulations, which are published at the end of every biennium (two-year period). The Model Regulations provide a uniform basis for the transport of dangerous materials around the world. The intent is that these documents will be used by governments and other organizations, such as the U.S.

Department of Transportation (DOT), International Air Transport Association (IATA), etc., when revising or developing regulations. Usually, there is a two-year lag time between the publication of the Model Regulations and the adoption of any changes by governments and other organizations, although that time has dwindled significantly over the past few years.

The most recent biennium concluded in December 2002. Those sessions produced some sweeping changes in the area of infectious material transport. For shipping purposes, infectious agents are now classified into two general categories. Category A agents are essentially Risk Group 4 and Select Agents. The Model Regulations provide an "indicative" list. These agents are assigned a UN Number of 2814 if they are "infectious substances affecting humans," or a UN Number of 2900 if they are "infectious substances affecting animals only." Category B infectious agents are defined as those that do not meet the criteria for Category A. These need to be shipped as UN3373, and the proper shipping name is "Diagnostic" or "Clinical specimens." Dr. Nicoletta Previsani from WHO had discussed these measures at the 2001 ABSA conference. A year previous to that meeting she had brought together a working group of technical experts who devised this schema for determining risk categories and reported their recommendations.

The packaging requirements have also changed. Category A agents must now be shipped according to Packing Instructions P620, basically infectious

substance packaging requirements. The Category B agents and diagnostic/clinical specimens need to be shipped using Packing Instructions P650. The latter requires triple packaging, but the outer shipper needs only minimal testing, as opposed to the rigorous requirements for P620. This allows for a much wider range of materials that can be used for this purpose.

Security was a major area of concern for the subcommittee. Since they wanted to assure that transporters had sufficient information to deal with the materials, but not to make the exact strain of the organism obvious to someone viewing the packages, they removed the requirement for the technical name to appear on the outer shipper. The technical name will remain on the paperwork and the inner documentation.

I am sure that some of you are puzzling over how some of these decisions/wording came about. It was a revelation to me to see firsthand the difficulty in trying to get resolutions through the UN process. The science of the issue is not the only consideration in making a decision. In many cases, compromises are made to push modest changes forward. The overall biosafety expertise is rather limited on the committee. Aside from WHO, only a handful of countries have individuals with some level of biosafety knowledge. Fortunately, when technical issues arise, those individuals and the interested parties get together and come to some agreement on the issue. This is why some of the recommendations seem a bit stilted—because they were compromise positions and required a lot of negotiating. The amazing thing about the entire process is that it ultimately succeeds in bringing about change.

Although great strides have been made with the current changes, a number of issues—such as the term “culture”—still need clarification/revision. It might be useful for ABSA to provide an up-to-date listing of the Category A and B agents. Additional issues such as large-scale waste transport and blood products still need attention, and I’m sure more will surface as the next meeting approaches.

Penny Holeman established an ABSA UN Transportation Working Group in conjunction with the Technical Review Committee. I will also be util-

izing this group. If you have expertise in this area, and/or would be interested in participating in this group, please let me know. You can contact me via e-mail at mary.cipriano@abbott.com.

What follows is a more detailed summary of the changes that was prepared by Linda Hume-Sastre, who is the Expert from Canada and chaired the working group that spearheaded these changes.

## **Changes to the UN Model Regulations, 13th Edition**

### **2.6.3 Division 6.2—Infectious substances**

#### **2.6.3.1 Definitions**

**2.6.3.1.1—Infectious substances** are substances which are known or are reasonably expected to contain pathogens. Pathogens are defined as microorganisms (including bacteria, viruses, rickettsiae, parasites, fungi), and other agents such as prions, which can cause disease in humans or animals.

**2.6.3.1.2—Biological products** are those products derived from living organisms which are manufactured and distributed in accordance with the requirements of appropriate national authorities, which may have special licensing requirements, and are used either for prevention, treatment, or diagnosis of disease in humans or animals, or for development, experimental or investigational purposes related thereto. They include, but are not limited to, finished or unfinished products such as vaccines.

**2.6.3.1.3—Cultures** (laboratory stocks) are the result of a process by which pathogens are amplified or propagated in order to generate high concentrations thereby increasing the risk of infection when exposure to them occurs. This definition refers to cultures prepared for the intentional generation of pathogens and does not include cultures intended for diagnostic and clinical purposes.

**2.6.3.1.4—Genetically modified microorganisms and organisms** are microorganisms and organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally.

**2.6.3.1.5—Medical or clinical wastes** are wastes derived from the medical treatment of animals or humans or from bio-research.

### 2.6.3.2 Classification of infectious substances

2.6.3.2.1—Infectious substances shall be classified in Division 6.2 and assigned to UN 2814, UN 2900 or UN 3373, as appropriate.

#### 2.6.3.2.2 Infectious substances are divided into the following categories.

2.6.3.2.2.1—Category A: An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease to humans or animals. Indicative examples of substances that meet these criteria are given in the table in this paragraph.

Note: An exposure occurs when an infectious substance is released outside of the protective packaging, resulting in physical contact with humans or animals.

(a) Infectious substances meeting these criteria which cause disease in humans or both in humans and animals shall be assigned to UN 2814. Infectious substances which cause disease only in animals shall be assigned to UN 2900.

(b) Assignment to UN 2814 or UN 2900 shall be based on the known medical history and symptoms of the source human or animal, endemic local conditions, or professional judgment concerning individual circumstances of the source human or animal.

Note 1: The proper shipping name for UN 2814 is INFECTIOUS SUBSTANCE, AFFECTING HUMANS. The proper shipping name for UN 2900 is INFECTIOUS SUBSTANCE, AFFECTING ANIMALS ONLY.

Note 2: Table 1 is not exhaustive. Infectious substances, including new or emerging pathogens, which do not appear in the table but which meet the same criteria should be assigned to Category A. In addition, if there is doubt as to whether or not a substance meets the criteria it shall be included in Category A.

Note 3: The micro-organisms in Table 1 are written in italics are bacteria, mycoplasmas, rickettsia or fungi.

2.6.3.2.2.2—Category B: An infectious substance which does not meet the criteria for inclusion

in Category A. Infectious substances in Category B shall be assigned to UN 3373 except that cultures as defined in 2.6.3.1.3 shall be assigned to UN 2814 or UN 2900 as appropriate.

Note: The proper shipping name for UN3373 is "DIAGNOSTIC or CLINICAL SPECIMENS."

2.6.3.2.3—Substances which do not contain infectious substances or substances which are unlikely to cause disease in humans or animals are not subject to these Regulations unless they meet the criteria for inclusion in another class.

2.6.3.2.4—Blood or blood components which have been collected for the purpose of transfusion or for the preparation of blood products to be used for transfusion or transplantation and any tissues or organs intended for use in transplants are not subject to these Regulations.

2.6.3.2.5—Substances for which there is a low probability that infectious substances are present, or where the concentration is at a level naturally encountered, are not subject to these Regulations. Examples are: foodstuffs, water samples, living persons and substances which have been treated so that the pathogens have been neutralized or deactivated.

2.6.3.2.6—An animal which has been intentionally infected and is known or suspected to contain an infectious substance shall only be transported under terms and conditions approved by the competent authority.

### 2.6.3.3 Biological products

2.6.3.3.1—For the purposes of these Regulations, biological products are divided into the following groups:

(a) those which are manufactured and packaged in accordance with the requirements of appropriate national authorities and transported for the purposes of final packaging or distribution, and use for personal health care by medical professionals or individuals. Substances in this group are not subject to these Regulations.

(b) those which do not fall under paragraph (a) and are known or reasonably believed to contain infectious substances and which meet the criteria for inclusion in Category A or Category B. Substances in this group shall be assigned to UN 2814, UN 2900 or UN 3373, as appropriate.

**Table 1**

| Indicative examples of infectious substances included in Category A in any form unless otherwise indicated.<br>(2.6.3.2.2.(a)) |   |
|--|---|
| UN Number and Proper Shipping Name   | Micro-organism  |
| UN 2814<br>Infectious substances affecting humans  | <p>Bacillus anthracis (cultures only)</p> <p><i>Brucella abortus</i> (cultures only)</p> <p><i>Brucella melitensis</i> (cultures only)</p> <p><i>Brucella suis</i> (cultures only)</p> <p><i>Burkholderia mallei</i>–<i>Pseudomonas mallei</i>–Glanders (cultures only)</p> <p><i>Burkholderia pseudomallei</i>–<i>Pseudomonas pseudomallei</i> (cultures only)</p> <p><i>Chlamydia psittaci</i>–avian strains (cultures only)</p> <p><i>Clostridium botulinum</i> (cultures only)</p> <p><i>Coccidioides immitis</i> (cultures only)</p> <p><i>Coxiella burnetii</i> (cultures only)</p> <p>Crimean-Congo hemorrhagic fever virus</p> <p>Dengue virus (cultures only)</p> <p>Eastern equine encephalitis virus (cultures only)</p> <p><i>Escherichia coli</i>, verotoxigenic (cultures only)</p> <p>Ebola virus</p> <p>Flexal virus</p> <p><i>Francisella tularensis</i> (cultures only)</p> <p>Guanarito virus</p> <p>Hantaan virus</p> <p>Hantaviruses causing hantavirus pulmonary syndrome</p> <p>Hendra virus</p> <p>Hepatitis B virus (cultures only)</p> <p>Herpes B virus (cultures only)</p> <p>Human immunodeficiency virus (cultures only)</p> <p>Highly pathogenic avian influenza virus (cultures only)</p> <p>Japanese Encephalitis virus (cultures only)</p> <p>Junin virus</p> <p>Kyasanur Forest disease virus</p> <p>Lassa virus</p> <p>Machupo virus</p> <p>Marburg virus</p> <p>Monkeypox virus</p> <p><i>Mycobacterium tuberculosis</i> (cultures only)</p> <p>Nipah virus</p> <p>Omsk hemorrhagic fever virus</p> <p>Poliovirus (cultures only)</p> <p>Rabies virus</p> <p><i>Rickettsia prowazekii</i> (cultures only)</p> <p><i>Rickettsia rickettsii</i> (cultures only)</p> <p>Rift Valley fever virus</p> <p>Russian spring-summer encephalitis virus (cultures only)</p> <p>Sabia virus</p> <p><i>Shigella dysenteriae</i> type 1 (cultures only)</p> <p>Tick-borne encephalitis virus (cultures only)</p> <p>Variola virus</p> <p>Venezuelan equine encephalitis virus</p> <p>West Nile virus (cultures only)</p> <p>Yellow fever virus (cultures only)</p> <p><i>Yersinia pestis</i> (cultures only)</p> |

**Table 2**

| Indicative examples of infectious substances included in Category A in any form unless otherwise indicated.<br>(2.6.3.2.2.(a)) |  |
|--|--|
| UN Number and Proper Shipping Name   | Micro-organism   |
| UN 2900<br>Infectious substances affecting animals only  | African horse sickness virus<br>African swine fever virus<br>Avian paramyxovirus Type 1—Newcastle disease virus<br>Bluetongue virus<br>Classical swine fever virus<br>Foot and mouth disease virus<br>Lumpy skin disease virus<br><i>Mycoplasma mycoides</i> —Contagious bovine pleuropneumonia<br>Peste des petits ruminants virus<br>Rinderpest virus<br>Sheep-pox virus<br>Goatpox virus<br>Swine vesicular disease virus<br>Vesicular stomatitis virus |

**Note:** Some licensed biological products may present a biohazard only in certain parts of the world. In that case, competent authorities may require these biological products to be in compliance with local requirements for infectious substances or may impose other restrictions.

#### 2.6.3.4 Genetically modified micro-organisms and organisms

2.6.3.4.1—Genetically modified micro-organisms not meeting the definition of an infectious substance shall be classified according to Chapter 2.9.

#### 2.6.3.5 Medical or clinical wastes

2.6.3.5.1—Medical or clinical wastes containing Category A infectious substances or containing Category B infectious substances in cultures shall be assigned to UN 2814 or UN 2900 as appropriate. Medical or clinical wastes containing infectious substances in Category B, other than cultures, shall be assigned to UN 3291.

2.6.3.5.2—Medical or clinical wastes which are reasonably believed to have a low probability of containing infectious substances shall be assigned to UN 3291.

**Table 3**  
Dangerous Goods List

| UN No<br>(1) | Name and description<br>(2)                 | Class or Division<br>(3) | Sub. risk<br>(4) | PG<br>(5) | SP<br>(6) | LQ<br>(7) | Packaging and IBCs |           | Portable Tanks |            |
|--------------|---|--------------------------|------------------|-----------|-----------|-----------|--------------------|-----------|----------------|------------|
|              |   |                          |                  |           |           |           | PI<br>(8)          | PP<br>(9) | T<br>(10)      | TP<br>(11) |
| 2814         | Infectious Substance Affecting Humans       | 6.2                      |                  |           | 318       | None      | P620               |           |                |            |
| 2900         | Infectious Substance Affecting Animals Only | 6.2                      |                  |           | 318       | None      | P620               |           |                |            |
| 3373         | Diagnostic or Clinical Specimens            | 6.2                      |                  |           | 319       | None      | P650               |           |                |            |

**Note:** The proper shipping name for UN 3291 is CLINICAL WASTE, UNSPECIFIED, N.O.S. or (BIO) MEDICAL WASTE, N.O.S. or REGULATED MEDICAL WASTE, N.O.S.

2.6.3.5.3—Decontaminated medical or clinical wastes which previously contained infectious substances are not subject to these Regulations unless they meet the criteria for inclusion in another class.

## Special Provisions

Special Provision 274, requiring the technical name, is deleted from UN 2814 and UN 2900.

Special Provision 318 applies and reads as follows:

“318. For the purposes of documentation, the proper shipping name shall be supplemented with the technical name (see 3.1.2.8). Technical names need not be shown on the package. When the infectious substances to be transported are unknown, but suspected of meeting the criteria for inclusion in Category A and assignment to UN 2814 or UN 2900, the words “suspected category A infectious substance” shall be shown, in parentheses, following the proper shipping name on the transport document but not on the outer packagings.”

Special Provision 319 is against UN 3373, Diagnostic or Clinical Specimens

“319. This entry applies to human or animal

material including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluids, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment or prevention. Substances packed and marked in accordance with packing instruction P650 are not subject to any other requirements in these Regulations.”

4.1.8.3—For UN 281 and UN 2900, an itemized list of contents shall be enclosed between the secondary packaging and the outer packaging. When the infectious substances to be transported are unknown but suspected of meeting the criteria for inclusion in Category A and assignment to UN 2814 or UN 2900, the words “suspected category A infectious substance” shall be shown, in parentheses, following the proper shipping name on the document inside the outer packaging.


### 7.1.6.2.3 Decontamination of transport units

A railway wagon, road vehicle, cargo space of a ship, compartment of an aircraft or other transport unit which has been used to transport infectious substances shall be inspected or release of the substance before re-use. If the infectious substances were released during transport, the transport unit shall be decontaminated before it is re-used. Decontamination may be achieved by any means which effectively inactivates the released infectious substance.

**Table 4**  
Packaging Instructions

| P620   | Packing Instruction | P620 |
|--|---------------------|------|
| This instruction applies to UN Nos. 2814 and 2900.   |                     |      |
| The following packagings are authorized provided the special packing provisions of 4.1.8 are met:  |                     |      |
| Packagings meeting the requirements of Chapter 6.3 and approved accordingly consisting of:   |                     |      |
| (a) Inner packagings comprising:   |                     |      |
| (i) watertight primary receptacle(s);  |                     |      |
| (ii) a watertight secondary packaging;   |                     |      |
| (iii) other than for solid infectious substances, an absorbent material in sufficient quantity to absorb the entire contents placed between the primary receptacle(s) and the secondary packaging; if multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated so as to prevent contact between them;   |                     |      |
| (b) A rigid outer packaging of adequate strength for its capacity, mass and intended use. The smallest external dimension shall be not less than 100 mm.   |                     |      |
| <b>Additional requirements:</b>  |                     |      |
| 1. Inner packagings containing infectious substances shall not be consolidated with inner packagings containing unrelated types of goods. Complete packages may be overpacked in accordance with the provisions of 1.2.1 and 5.1.2: such an overpack may contain dry ice.  |                     |      |
| 2. Other than for exceptional consignments, e.g., whole organs which require special packaging, the following additional requirements shall apply:   |                     |      |
| (a) Substances consigned at ambient temperatures or at a higher temperature. Primary receptacles shall be of glass, metal or plastics. Positive means of ensuring a leakproof seal shall be provided, e.g., a heat seal, a skirted stopper or a metal crimp seal. If screw caps are used, they shall be secured by positive means, e.g., tape, paraffin sealing tape or manufactured locking closure;  |                     |      |
| (b) Substances consigned refrigerated or frozen. Ice, dry ice or other refrigerant shall be placed around the secondary packaging(s) or alternatively in an overpack with one or more complete packages marked in accordance with 6.3.1.1. Interior supports shall be provided to secure secondary packaging(s) or packages in position after the ice or dry ice has dissipated. If ice is used, the outer packaging or overpack shall be leakproof. If dry ice is used, the outer packaging or overpack shall permit the release of carbon dioxide gas. The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the refrigerant used; |                     |      |
| (c) Substances consigned in liquid nitrogen. Plastics primary receptacles capable of withstanding very low temperature shall be used. The secondary packaging shall also be capable of withstanding very low temperatures, and in most cases will need to be fitted over the primary receptacle individually. Provisions for the consignment of liquid nitrogen shall also be fulfilled. The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the liquid nitrogen.  |                     |      |
| (d) Lyophilized substances may also be transported in primary receptacles that are flame-sealed glass ampoules or rubber-stoppered glass vials fitted with metal seals;  |                     |      |
| 3. <i>Whatever the intended temperature of the consignment, the primary receptacle or the secondary packaging shall be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 kPa and temperatures in the range -40°C to +55°C.</i>  |                     |      |

**Table 5**  
Packaging Instructions

| P650   | Packing Instruction | P650 |
|--|---------------------|------|
| <p>This packing instruction applies to UN 3373</p> <ol style="list-style-type: none"><li>(1) The packaging shall be of good quality, strong enough to withstand the shocks and loadings normally encountered during transport, including transshipment between transport units and between transport units and warehouses as well as any removal from a pallet or overpack for subsequent manual or mechanical handling. Packagings shall be constructed and closed to prevent any loss of content that might be caused under normal conditions of transport by vibration or by changes in temperature, humidity or pressure.</li><li>(2) The packaging shall consist of three components:<ol style="list-style-type: none"><li>(a) a primary receptacle,</li><li>(b) a secondary packaging, and</li><li>(c) an outer packaging.</li></ol></li><li>(3) Primary receptacles shall be packed in secondary packagings in such a way that, under normal conditions of transport, they cannot break, be punctured or leak their contents into the secondary packaging. Secondary packagings shall be secured in outer packagings with suitable cushioning material. Any leakage of the contents shall not compromise the integrity of the cushioning material or of the outer packaging.</li><li>(4) For transport, the mark illustrated below shall be displayed on the external surface of the outer packaging on a background of a contrasting colour and shall be clearly visible and legible. The width of the line shall be at least 2 mm; the letters and numbers shall be at least 6 mm high.</li></ol> |                     |      |
|    |                     |      |
| <ol style="list-style-type: none"><li>(5) The completed package shall be capable of successfully passing the drop test in 6.3.2.5 as specified in 6.3.2.3 and 6.3.2.4 of the Model Regulations except that the height of the drop shall not be less than 1.2 m.</li></ol>  |                     |      |

**Table 5 (continued)**  
Packaging Instructions

| P650 | Packing Instruction  | P650 |
|------|--|------|
|      | <p>(6) For liquid substances</p> <ul style="list-style-type: none"> <li>(a) The primary receptacle(s) shall be leakproof.</li> <li>(b) The secondary packaging shall be leakproof.</li> <li>(c) If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them.</li> <li>(d) Absorbent material shall be placed between the primary receptacle(s) and the secondary packaging. The absorbent material shall be in quantity sufficient to absorb the entire contents of the primary receptacle(s) so that any release of the liquid substances will not compromise the integrity of the cushioning material or of the outer packaging.</li> <li>(e) The primary receptacle or the secondary packaging shall be capable of withstanding, without leakage, an internal pressure of 95 kPa (0.95 bar).</li> </ul> <p>(7) For solid substances:</p> <ul style="list-style-type: none"> <li>(a) The primary receptacle(s) shall be siftproof.</li> <li>(b) The secondary packaging shall be siftproof.</li> <li>(c) If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them.</li> </ul> <p>(8) Refrigerated or frozen specimens: Ice, Dry ice and liquid nitrogen</p> <ul style="list-style-type: none"> <li>(a) When dry ice or liquid nitrogen is used to keep specimens cold, all applicable requirements of these Regulations shall be met. When used, ice or dry ice shall be placed outside the secondary packagings or in the outside packaging or an overpack. Interior supports shall be provided to secure the secondary packagings in the original position after the ice or dry ice has dissipated. If ice is used, the outside packaging or overpack shall be leakproof. If Carbon dioxide, solid (dry ice) is used, the packaging shall be designed and constructed to permit the release of carbon dioxide gas to prevent a build-up of pressure that could rupture the packagings and shall be marked "Carbon dioxide, solid" or "Dry ice."</li> <li>(b) The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures that could result if refrigeration were lost.</li> </ul> <p>(9) Infectious substances assigned to UN 3373 which are packed and marked in accordance with this packing instruction are not subject to any other requirement in these Regulations.</p> <p>(10) Clear instructions on filling and closing such packages shall be provided by packaging manufacturers and subsequent distributors to the consignor or to the person who prepares the package (e.g. patient) to enable the package to be correctly prepared for transport.</p> |      |